NxStage Medical, Inc.
NxStage Express Fluid Warmer
Special 510(k) Device Modification

JUN 16 2014

This 510(k) Summary is being submitted in accordance with the requirements of the Safe Medical Device Act (SMDA) of 1990. The content contained in this 510(k) summary has been provided in conformance with 21 CFR §807.92

A. Date of Preparation May 21, 2014

B. Submitter's Information:

Name:	NxStage Medical, Inc.
Address:	350 Merrimack Street Lawrence, MA 01843
FDA Establishment Owner/Operator Number:	9045797
Contact Person:	Mary Lou Stroumbos Director, Regulatory Affairs
Phone:	(978) 687-4872
Fax:	(978) 687-4750
Manufacturer:	NxStage Medical, Inc. 350 Merrimack Street Lawrence, MA 01843
FDA Establishment Registration Number:	3003464075
Sterilization Site:	Steris Isomedix 1000 S. Sarah Place Ontario, CA 91761

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B. Device Name:

Trade Name:	NxStage Express Fluid Warmer
Common/Usual Name:	Monitor, Temperature, Dialysis
Classification Name:	Hemodialysis System and Accessories (876.5820) Product Code: 78 FLA

C. Substantial Equivalence/Predicate Devices:

The proposed NxStage Express Fluid Warmer is substantially equivalent to the NxStage Travel Warmer cleared through K071263 on August 24, 2007.

D. Device Description/Indications for Use:

The NxStage Express Fluid Warmer is an accessory to the NxStage System One used to warm dialysate prior to administration. The Express Fluid Warmer is for use with the NxStage System One only and is not used to warm blood or blood products. The Express Fluid Warmer consists of an electro-mechanical warming unit and a single-use disposable.

Indications for use:

The NxStage Express Fluid Warmer and Express Fluid Warmer Disposable Set are accessories to the NxStage System One Cycler used to warm dialysate prior to administration.

E. Technological Characteristics:

The proposed device has the same technological characteristics and is similar in design and configuration as compared to the predicate device. The proposed device is designed with similar software, components and features also used in the predicate device as shown in Table 1.

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Table 1
Device Technological Characteristics Comparison Table

Parameter	Proposed Device NxStage Express Fluid Warmer	Predicate Device NxStage Travel Warmer (K071263)
Indications for Use	The NxStage Express Fluid Warmer and Express Fluid Warmer Disposable Set are accessories to the NxStage System One Cycler used to warm dialysate prior to administration.	The NxStage Travel Warmer and Travel Warmer Disposable set are accessories to the NxStage System One used to warm dialysate prior to administration
Heating Method	Same	One Aluminum plate heated by electrical resistance
Fluid Temperatures	Same	31°C – 38°C Adjustable
Temperature Control	Same	Thermistors
Alarm Logic		
a) Upper limit	Same	Alarms activate when temperature reaches 41°C
b) Lower Limit	N/A	N/A
Alarms	Same	Audible and Visual

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Table 1
Device Technological Characteristics Comparison Table

Parameter	Proposed Device NxStage Express Fluid Warmer	Predicate Device NxStage Travel Warmer (K071263)
Secondary Safety Mechanism	Same	Hardware safety circuit cuts the power to the heater if the fluid temperature is ≥ 41°C for more than 5 seconds
Fluid Flow Rates	Same	0 – 200 ml/min
Control System	Same	Microcontroller
Voltage	100-120/230 VAC Auto ranging	110 -240 VAC
Power	Same	400 VA
Frequency	Same	50/60 Hz
Mounting Method	Same	Top Mount with IV pole support
Dimensions	Same	13"W X 10"L X 1 ½ "H
Material	Same	PVC, ABS

Table 1
Device Technological Characteristics Comparison Table

Parameter	Proposed Device NxStage Express Fluid Warmer	Predicate Device NxStage Travel Warmer (K071263)
Fluid warming Method	Same	5L Dialysate Bag with connectors to MLA and therapy fluid outlet line
Method of air removal	Same	Air entrapment in bag – release not required due to large bag capacity
Priming Volume	Same	100 ml
Method of Sterilization	Same	Gamma SAL 10^{-6}
Pyrogenicity	Same	Non-pyrogenic
Packaging	Same	Packaged in polyethylene bags
Single/ Multiple Use	Same	Single Use only

F. Summary of Non-Clinical Test/Performance Testing - Bench

NxStage believes that the information and data provided in this submission clearly describes the proposed device and demonstrates that the device is adequately designed for the labeled indications for use. Performance, verification and validation testing was conducted to characterize performance of the proposed NxStage Express Fluid Warmer to provide a basis of comparison to the predicate device. Results of the all testing have documented that the proposed NxStage Express Fluid Warmer is substantially equivalent to the predicate device and is suitable for the labeled indications for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 16, 2014

NxStage Medical, Inc.
Mary Lou Stroumbos
Director, Regulatory Affairs
350 Merrimack Street
Lawrence, MA 01843

Re: K140623
Trade/Device Name: NxStage Express Fluid Warmer
Regulation Number: 21 CFR§ 876.5820
Regulation Name: Hemodialysis system and accessories
Regulatory Class: II
Product Code: FLA
Dated: May 21, 2014
Received: May 22, 2014

Dear Mary Lou Stroumbos,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K140623

Device Name: NxStage Express Fluid Warmer

Indications for Use: The NxStage Express Fluid Warmer and Express Fluid Warmer Disposable Set are accessories to the NxStage System One Cycler used to warm dialysate prior to administration.

Prescription Use ___X___ **AND/OR** **Over-The-Counter Use**_____
(Part 21 CFR 801 Subpart D) **(21 CFR 807 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Benjamin R. Fisher -S
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